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Onconova Announces Enrollment of First Patient in Japan by SymBio

Global Phase 3 INSPIRE Trial of Rigosertib in Higher-Risk Myelodysplastic Syndromes Now Active in More than 90 Sites

NEWTOWN, Pa., July 19, 2016 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ:ONTX), a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced the enrollment of the first patient in Japan by SymBio Pharmaceuticals in the global Phase 3 INSPIRE trial, investigating IV rigosertib as a treatment for higher-risk (HR) myelodysplastic syndromes (MDS) following failure of hypomethylating agent (HMA) therapy. SymBio licensed rights to rigosertib from Onconova for Japan and Korea in 2011 and has completed two Phase 1 trials in Japan.

The INSPIRE pivotal trial is now open for patient enrollment in more than 90 sites in the U.S., Europe, Canada, Australia, Israel and Japan. The first patient in this trial was enrolled in December 2015, and so far, patients have been enrolled in six countries on four continents.

"We are pleased to be participating in the Phase 3 INSPIRE trial for HR-MDS patients," said Fuminori Yoshida, President and CEO of SymBio. "The enrollment of the first patient in Japan for this pivotal Phase 3 trial marks an important milestone for SymBio. We believe that rigosertib has the potential to address important unmet medical needs of MDS patients in Japan. As such, beyond our participation in this study, we have also completed two Phase 1 studies and are now preparing to enroll patients in a Japanese Phase 1 trial of oral rigosertib plus azacitidine in patients with MDS."

"The initiation of the Phase 3 INSPIRE trial in Japan represents an important achievement in our collaboration with SymBio," commented Ramesh Kumar, Ph.D., President and CEO of Onconova. "In addition to participating in this trial, SymBio is also playing a key role in Japan in the development of single-agent oral rigosertib and oral rigosertib in combination with azacitidine. We look forward to providing periodic updates on the progress of the INSPIRE trial and publications and scientific presentations related to rigosertib."

The INSPIRE trial is a multi-center, randomized controlled Phase 3 study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed, following previous treatment with HMAs. The trial will enroll approximately 225 patients randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. It is anticipated that more than 130 sites across four continents (North America, Europe, Australia and Asia) will participate in this trial. The primary endpoint of INSPIRE is overall survival and an interim analysis is anticipated.

About INSPIRE

The **IN**ternational **S**tudy of **P**hase III **I**V **R**igos**E**rtib, or INSPIRE, is based on guidance received from the U.S. Food and Drug Administration and European Medicines Agency and derives from the findings of the ONTIME Phase 3 trial. INSPIRE is a multi-center, randomized controlled study to assess the efficacy and safety of IV rigosertib in HR-MDS patients who had progressed on, failed to respond to, or relapsed after previous treatment with an HMA within the first nine months of initiation of HMA treatment. This time frame optimizes the opportunity to respond to treatment with an HMA prior to declaring treatment failure, as per NCCN Guidelines.[1] The trial will enroll approximately 225 patients randomized at a 2:1 ratio into two treatment arms: IV rigosertib plus Best Supportive Care versus Physician's Choice plus Best Supportive Care. The primary endpoint of INSPIRE is overall survival and an interim analysis is anticipated. Full details of the INSPIRE trial, such as inclusion and exclusion criteria, as well as secondary endpoints, can be found on clinicaltrials.gov (NCT02562443).

About Rigosertib

Rigosertib is a small molecule inhibitor of cellular signaling and acts as a Ras mimetic. These effects of rigosertib appear to be mediated by direct binding of the compound to the Ras-binding domain (RBD) found in many Ras effector proteins, including the Raf kinases and PI3K. The therapeutic focus for rigosertib is myelodysplastic syndromes (MDS), a group of bone marrow disorders characterized by ineffective formation of blood cells that often converts into acute myeloid leukemia (AML). Clinical trials for rigosertib are being conducted at leading institutions in the U.S., Europe, and the Asia-Pacific region. Both the Intravenous (IV) and oral formulations of rigosertib are being tested in multiple clinical trials. Rigosertib is protected by issued patents (earliest expiry in 2026) and has been awarded Orphan Designation for MDS in the U.S.,

Europe and Japan.

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a Phase 3 clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. In addition to rigosertib, the Company's most advanced product candidate, two other candidates are clinical stage, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

References

[1]National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 1.2016.

Forward Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements relate to future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, regulatory approvals, expectations regarding the sufficiency of Onconova's cash and other resources to fund operating expenses and capital expenditures, Onconova's anticipated milestones and future expectations and plans and prospects. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including Onconova's need for additional financing and current plans and future needs to scale back operations if adequate financing is not obtained, the success and timing of Onconova's clinical trials and regulatory approval of protocols, and those discussed under the heading "Risk Factors" in Onconova's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q.

Any forward-looking statements contained in this release speak only as of its date. Onconova undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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